

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the above-identified application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 1-12 have been canceled, without prejudice or disclaimer to the subject matter disclosed therein. New claims 13-142 have been added. Support for new claims 13-142 may be found in the specification as filed.

**Rejection of Claims 6-8 Under 35 U.S.C. § 101**

Claims 6-8 have been rejected under 35 U.S.C. § 101 for purportedly being directed to non-statutory subject matter. Claims 6-8 have been canceled by the foregoing amendment, thereby rendering their rejection moot. Furthermore, no new claims have been added which correspond to the subject matter of previous claims 6-8. In light of the cancellation of claims 6-8, withdrawal of this rejection under 35 U.S.C. § 101 is respectfully requested.

**Rejection of Claims 1-12 Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-12 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. Claims 1-12 have been canceled by the foregoing amendment, thereby rendering their rejection moot. Furthermore, the newly added claims

are believed to conform with U.S. patent practice and more clearly represent the invention. It is further believed that the new claims address all of the concerns of the Examiner regarding previous claims 1-12. In light of the cancellation of claims 1-12, withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**Rejection of Claims 6-12 Under 35 U.S.C. § 102(b)**

Claims 6-12 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Nair et al. Claims 6-12 have been canceled, thus rendering their rejection moot. This rejection, however, will be discussed as it may pertain to the currently pending claims. For at least all of the reasons set forth below, applicants respectfully request withdrawal of this rejection.

The present invention relates to an isolated epitope or antigen associated with impaired peptide processing. The isolated epitope or antigen of the present invention is expressed on target cells in which cellular peptide processing for MHC presentation has been impaired and is recognized by T-lymphocytes or T-cell receptors, or parts thereof. The recognition of the isolated epitope or antigen of the present invention by T-lymphocytes or T-cell receptors is increased if peptide processing for MHC presentation on said target cell is decreased. The present invention further relates to pharmaceutical compositions or vaccines comprising the isolated epitope or antigen of the present invention, and methods for preparing such pharmaceutical compositions or vaccines. The present invention also relates to methods for treating, preventing or diagnosing cancer or viral infections and for eliciting or stimulating T-lymphocytes or T-cell receptors or parts

thereof. Finally, the present invention relates to pharmaceutical compositions or vaccines comprising lymphoid cells or molecules specific for the isolated antigens or epitopes of the present invention.

Nair et al discloses treating cells with an anti-sense oligonucleotide specific for the TAP-2 gene, pulsing these cells with an OVA peptide, and subsequently testing these cells *in vitro* and *in vivo* to determine if they can elicit a CTL response against said OVA peptide (see page 1776, column 2, the first, second and third full paragraphs). The inhibition of cellular peptide processing was used as a means to increase the density of the externally added peptides on the cell surface of the inhibited cells, thereby achieving increased immunogenicity of the externally loaded peptides. In other words, the inhibited cells were used as immunization vehicles for the external antigen. Thus, Nair et al discloses a means of increasing the CTL response to exogenous peptides by exogenously introducing peptides to cells which have impaired TAP-2 cellular peptide processing.

Nair et al does not disclose or suggest each of the aspects of the present invention. The present invention relates to an isolated epitope or antigen associated with impaired peptide processing. The present invention also relates to methods for stimulating T-lymphocytes or T-cell receptors or parts thereof against an isolated epitope or antigen associated with impaired peptide processing. The isolated epitopes or antigens of the present invention are endogenously produced by a cell which has its cellular peptide processing impaired (see, for example, page 4, lines 8-12, of the specification as filed). Nair et al does not disclose or suggest methods for stimulating T-lymphocytes against peptides which are endogenously produced by a cell which has its cellular peptide

processing impaired. Nair et al did not test the ability of CTLs to recognize endogenously produced peptides. Thus, Nair et al does not disclose or suggest the present invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

**Rejection of Claims 6-9 Under 35 U.S.C. § 102(b)**

Claims 6-9 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Franksson et al. Claims 6-9 have been canceled, thus rendering their rejection moot. This rejection will be discussed as it may pertain to the currently pending claims. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Franksson et al discloses a means to illicit a CTL response to cells which have inhibited TAP-2 dependent cellular peptide processing. Franksson et al used fragments from RMA cells (which have normal cellular peptide processing) to sensitize RMA-S cells (which have impaired TAP-2 dependent cellular peptide processing) thereby allowing for CTL recognition of the RMA-S cells. See page 2608, columns 1 and 2, section 3.1. Franksson et al state that without sensitization of the RMA-S cells with exogenous fragments from the RMA cells, there was no CTL response (see column 1, the sentence starting 6 lines from the bottom, and Figure 1). The inhibition of cellular peptide processing was used as a means to increase the density of the externally added peptides on the cell surface of the inhibited cells, thereby achieving increased immunogenicity of the

externally loaded peptides. In other words, the inhibited cells were used as immunization vehicles for the external antigen.

Franksson et al does not disclose or suggest each of the aspects of the present invention. The present invention relates to an isolated epitope or antigen associated with impaired peptide processing. The present invention also relates to methods for stimulating T-lymphocytes or T-cell receptors or parts thereof against an isolated epitope or antigen associated with impaired peptide processing. The isolated epitopes or antigens of the present invention are endogenously produced by a cell which has its cellular peptide processing impaired (see, for example, page 4, lines 8-12, of the specification as filed). In contrast, Franksson et al disclose inducing a CTL response to exogenously introduced antigens present on a cell which has its cellular peptide processing impaired. Franksson et al did not test the ability of CTLs to recognize endogenously produced peptides. Thus, Franksson et al does not disclose or suggest the present invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).


### **CONCLUSION**

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

Respectfully submitted,

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Date: September 18, 2000